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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,033	05/09/2006	Rolf Berge	CU-4425 RJS	7417

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EXAMINER
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HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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04/22/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/550,033	<b>Applicant(s)</b> BERGE, ROLF	
	<b>Examiner</b> Raymond J. Henley III	<b>Art Unit</b> 1614	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 71-186 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 143-148, 151-160, 162-164 and 169-176 is/are allowed.
- 6) ☒ Claim(s) 71-75, 79-142, 149, 150, 161, 165-168 and 177-186 is/are rejected.
- 7) ☒ Claim(s) 76-78 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/14/06, 6/29/06</u> .  | 6) <input type="checkbox"/> Other: ____.                          |

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**CLAIMS 71-186 ARE PRESENTED FOR EXAMINATION**

Applicant's Preliminary Amendment filed May 9, 2006 and Information Disclosure Statements filed June 29, 2006 and September 14, 2006 have been received and entered into the application.

Accordingly, the claims have been amended as proposed and, as reflected by the attached, completed copies of form PTO-1449, the cited references have been considered.

***Claims Re-numbered***

In Applicant's Preliminary Amendment referenced above, a claim numbered as 177 is absent. Accordingly, under 37 C.F.R. 1.126, claims 178-187, as presented, have been renumbered as claims 177-187, respectively.

***Claim Rejection - 35 USC § 112, First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 71-74, 79, 81, 83, 85, 87, 89, 91, 93, 95, 97, 99, 101, 103, 105, 107, 109-121, 123, 124, 126, 127, 129, 130-134, 136, 138-141, rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of the various diseases and disorders, does not reasonably provide enablement for the prevention of such as well as the treatment/prevention of "cancer" in general. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims with a reasonable degree of success.

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In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988). These factors include:

- 1) the nature of the invention;
- 2) the breadth of the claims;
- 3) the predictability or unpredictability of the art;
- 4) the amount of direction or guidance presented;
- 5) the presence or absence of working examples;
- 6) the quantity of experimentation necessary;
- 7) the state of the prior art; and,
- 8) the relative skill of those skilled in the art.

Given the relevant factors there is insufficient evidence of record or knowledge in the art found by the Examiner that would support Applicant's contention that the claimed diseases could actually be prevented or the "cancer" in general could be treated and/or prevented. Applicant is reminded that the term "cancer" in the art refers to a plethora of cancer types which may or may not be related in their etiology or pathophysiology, and thus their treatment.

The Examiner acknowledges that the Office does not require the presence of working examples to be present in the disclosure of the invention (see MPEP §2164.02). However, in light of the state of the art, it does not seem possible that all listed diseases could be prevented and/or cancer could be treated and/or prevented. The Office would require appropriate disclosure to support the contention that the use of the claim specified active composition could actually prevent such a conditions by simply administering, by any method, an amount of the claimed active composition, especially in light of the fact that the present specification fails to enable one of ordinary skill in the art to practice the presently claimed method for preventing such a condition using the claimed active composition.

The term "prevention" or "preventing" is synonymous with the term "curing" and both circumscribe methods of treatment having absolute success. Since absolute success is not

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reasonably possible with most conditions, especially those having etiologies and pathophysiological manifestations that are as complex as those conditions claimed.

***Overcoming the Above Rejection***

Applicant may wish to consider deleting the term preventing from the claims as well as listing any specifically disclosed cancer types in order to overcome the above rejection.

***Claim Rejection - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 75, 77 and the claims dependent therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In these claims, Applicant has failed to apprise others of the metes and bounds of the expressions “improving the total lipid composition” and “improved fatty acid” such that one would be able to ascertain if a given invention is infringing upon Applicant’s subject matter.

In claims 90, 110 and 149, the term “Gendaxin®” fails to specify a particular compound or mixture of compounds because a copyrighted term does not refer to a specific compound/composition, (see MPEP § 2173.05(u)).

***Claim Objection***

Claims 76-78 are objected to as depending from a rejected base claim, but are otherwise in condition for allowance.

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*Allowable Claims*

Claims 143-148,151-160,162-164 and 169-176 are deemed allowable insofar as the Examiner has not been able to find any reference which would render the claimed subject matter anticipated or obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Raymond J Henley III/  
Primary Examiner  
Art Unit 1614

April 20, 2009